SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND SENIOR SCRIPTS

Senior Scripts, ("Licensee") and the State Board of Pharmacy ("Board") enter into this settlement agreement for the purpose of resolving the question of whether Licensee's license will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo,[1] the parties hereto waive the right to a hearing by the Administrative Hearing commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Licensee acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence on mitigation of discipline; and the right to request the recovery of attorney's fees incurred in defending this action against its license. Being aware of these rights provided to Licensee by operation of law, Licensee knowingly and voluntarily waives

[1] All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to it.

Licensee acknowledges that it has received a copy of the investigation report and other documents relied upon by the Board in determining there was cause for disciple, along with citations to law and/or regulations the Board believes were violated. For purpose of settling, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's pharmacy license, license number 1999135462, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

Joint Stipulation of Facts and Law

1. The Board is an agency of the State of Missouri created pursuant to Section 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Licensee holds a license from the Board as a pharmacy, license number 1999135462 ("License"). Licensee's license was current and active at all times relevant herein, and is presently still active.

3. On or about March 4, 2008, a complaint was filed with the Board regarding Licensee.

4. The Board conducted an investigation and found the following:

   A. The narcotic cabinet contained controlled substances accepted as returns from nursing homes.

B. Pharmacy technicians were emptying controlled substances out of OPUS containers containing returns from nursing homes.

C. Returned bags containing OPUS containers were not located within the pharmacy area and were accessible by any non-pharmacy personnel.

D. The narcotic cabinet contained an unlabeled vial of half tablet Methadone 10mg resulting in the drug being misbranded.

E. Pharmacy technicians and pharmacists did not use gloves as they filled nursing home containers.

F. The last controlled substance inventory was taken on March 14, 2007.

G. On April 29, 2008, an audit was conducted and the following losses reported:

   i. Lorazepam 0.5mg—2,413.5 tablets
   ii. Hydrocodone 5/500—3,963 tablets
   iii. Diazepam 5mg—27 tablets
   iv. Fentanyl 50mcg—28 patches

H. Lorazepam is a Schedule IV controlled substance pursuant to § 195.017.8(2)(aa), RSMo and 19 CSR 30-1.002.2(AA).

I. Hydrocodone 5/500 is a Schedule III controlled substance pursuant to § 195.017.6, RSMo, and 19 CSR 30-1.002.1(C)(4)(D).

J. Diazepam 5mg is a Schedule IV controlled substance pursuant to § 195.017.8(2)(n), RSMo, and 19 CSR 30-1.002.1(D)(2)(N).

K. Fentanyl is a Schedule II controlled substance pursuant to § 195.017.4(2)(j), RSMo, and 19 CSR 30-1.002.1(B)(2)(J).

L. Gina Giardina, ("Giardina"), worked at Senior Scripts as a pharmacy technician.

M. Giardina was not licensed as a pharmacy technician.

5. Section 338.055, RSMo, states in pertinent part:

* * *

2. The board may cause a complaint to be filed with the Administrative Hearing Commission as provided by Chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate or registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provisions of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government [.]

6. Section 196.015, RSMo, states:

> The following acts and the causing thereof within the state of Missouri are hereby prohibited:
>
> (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded [.]

7. Section 196.100, RSMo, Cum. Supp. 2008, states in part:

> 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

8. 20 CSR 2220-2.130 states in part:

> (D) Any prepackaged drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

9. 20 CSR 2220-2.010(1) states in part:

> * * *
>
> (F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions [.]

10. 19 CSR 30-1.042 states in part:

> (3) Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual

inventory may be taken on any date that is within one year of the previous annual inventory date.

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11. 20 CSR 2220-2.010(1) states in part:

(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility [.]

12. 19 CSR 30-1.031 states in part:

(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032.19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

13. 19 CSR 30-1.034(1) states in part:

(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(B) Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

14. Section 338.013, RSMo, states in pertinent part:

1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy

technician. Such applicant shall not have engaged in conduct or behavior determined to be grounds for discipline pursuant to this chapter. Such applicant shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

15. 20 CSR 2220-2.700 states in part:

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgment in connection with the receiving, preparing, compounding, distribution or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

16. Section 338.210, Cum. Supp. 2008, RSMo, states in part:

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

17. 20 CSR 2220-2.010(1) states:

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(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy lawas or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

Conclusions of Law

18. Because Licensee accepted returns of Schedule II drugs from nursing homes, it engaged in incompetency, misconduct, and/or gross negligence, providing cause to discipline its license pursuant to § 338.055.2(5), (13), and (15) RSMo.

19. Because Licensee maintained an unlabeled vial of half tablet Methadone in the narcotic cabinet, it engaged in incompetency, misconduct, and/or gross negligence, providing cause to discipline its license pursuant to § 338.055.2(5), (6), (13), and (15) RSMo.

20. Because Licensee allowed pharmacists and pharmacy technicians to fill nursing home prescription containers without wearing gloves, it engaged in incompetency, misconduct, and/or gross negligence, providing cause to discipline her license pursuant to § 338.055.2(5), (6), and (13) RSMo.

21. Because Licensee did not take a controlled substance inventory since March 14, 2007, it violated 19 CSR 30-1.042, providing cause to discipline its license pursuant to 20 CSR 2220-2.090 and § 338.055.2(5), (13), and (15), RSMo.

22. Because Licensee allowed an unlicensed individual to perform the duties of a pharmacy technician, it violated § 338.013.1, providing cause to discipline her license pursuant to § 338.055.2(6), (13), and (15), RSMo.

23. Because Licensee allowed the diversion of controlled substances, it engaged in incompetency, misconduct, and/or gross negligence, providing cause to discipline its license pursuant to § 338.055.2(5) and (15) RSMo.

24. Because Licensee allowed the diversion of controlled substances, it violated the professional trust and/or confidence with its customers and the general public, providing cause to discipline its license pursuant to § 338.055.2(13), RSMo.

25. Because Licensee allowed an unlicensed individual to perform the duties of a pharmacy technician, it assisted or enabled a person to practice or offer to practice as a pharmacy technician, a profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter pursuant to § 338.055.2(10), RSMo.

Jointly Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo.

1. Licensee's license as a pharmacist, License No. 1999135462, is hereby placed on **PROBATION** for three (3) years. The period of probation shall constitute the "disciplinary period." During the disciplinary period, Licensee shall be entitled to practice as a pharmacy under Chapter 338, RSMo, as amended, provided Licensee adheres to all the terms of this agreement.

2. **Terms and conditions of the disciplinary period.** The terms and conditions of the disciplinary period are as follows:

A. The parties to this agreement understand that the Board of Pharmacy will maintain this agreement as an open record of the Board as provided in Chapters 338, 610, and 620, RSMo.

B. Licensee shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

C. Licensee shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

D. If requested Licensee shall provide the Board a list of all licensed pharmacists employed by the Licensee, and the individuals' current home addresses and telephone numbers.

E. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

F. Licensee shall report to the Board, on a preprinted form supplied by the Board office, once every 6 months(due by each January 1 and July 1), beginning with whichever date occurs first after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

G. Licensee shall not serve as an intern training facility for interns.

H. Licensee shall select an independent consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Licensee shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of

probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial reports shall be provided within sixty (60) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a 6 month cycle and reports to the Board office will be provided once every 6 months throughout the disciplinary period. The consultant shall be hired at Licensee's expense.

3. Consultant shall perform an audit and reconciliation on all Schedule III and IV controlled substances on a semi-annual basis. The consultant shall report the results of each reconciliation to the Board's office.

4. Licensee shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Licensee will be notified and given sufficient time to arrange these meetings.

5. Licensee's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary agreement.

6. Upon the expiration of the disciplinary period, the license of Licensee shall be fully restored if all requirements of law have been satisfied; provided, however, that in the event the Board determines that Licensee has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing,

vacate and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline Licensee's license.

7. No additional discipline shall be imposed by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and opportunity for hearing before the Board as a contested case in accordance with the provisions of Chapter 536, RSMo.

8. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning any future violations by Licensee of Chapter 338, RSMo, as amended, or the regulations promulgated thereunder, or of the terms and conditions of this Settlement Agreement.

9. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning facts or conduct not specifically mentioned in this Settlement Agreement that are either now known to the Board or may be discovered.

10. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the parties agree that the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held, to determine whether a violation occurred and, if so, may impose further disciplinary action. Licensee agrees and stipulates that the Board has continuing jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

11. Each party agrees to pay all their own fees and expenses incurred as a result of this case, its litigation, and/or its settlement.

12. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

13. Licensee hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this settlement agreement in that is survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

14. Licensee understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's license as a pharmacist. If Licensee desires the Administrative hearing Commission to review this agreement, Licensee may submit its

request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102.

15. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect fifteen (15) days after the document is signed by the Executive Director of the Board.

LICENSEE

By:
Senior Scripts Pharmacy
753 Goddard Ave.
Chesterfield, MO 63005

Date 4-9-09

STATE BOARD OF PHARMACY

Kimberly Grinston, Executive Director
State Board of Pharmacy

Date 4-22-09

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